

BS 39. A method for manual retinal vein catheterization comprising inserting a microcatheter system within a retinal vein and infusing solution into the retinal vein, whereby the microcatheter system remains within the retinal vein without an external holding device.

### REMARKS

Claims 1-35 and 39-57 are pending in the subject application. Claim 20 has been cancelled, without prejudice. Claims 1-3, 21-23 and 39 have been amended. Support for the amendments to claims 1-3, 21-23 and 39 is found throughout the Specification, as filed, and no new matter is presented by the amendments.

Favorable reconsideration in light of the amendments and remarks which follow is respectfully requested.

#### 1. Drawings

The drawings have been objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the reference sign mentioned in the description: wire 30.

Upon review, Applicants have found a typographical error in the Specification wherein the wire is referred to as reference numeral 30 rather than 32. Thus, the Specification has been amended herein accordingly.

#### 2. Specification

The disclosure has been objected to because of the following informalities: page 15 of the specification references the larger cannula as #12 whereas the drawings use reference #14.

Upon review, Applicants have found that a typographical error was made on page 15 wherein the larger cannula was referred to as reference numeral 12 rather than 12. Thus, the Specification has been amended herein accordingly..

#### 3. 35 U.S.C. §112 Rejections

Claims 1, 5-33 and 39-57 have been rejected under 35 U.S.C. §112, second paragraph. The Office states that:

Claims 5, 8, 9, 12, 24, 25 and 39 recite the limitation "the flexible cannula" or "the cannula". There is insufficient antecedent basis for this limitation in claim 1 which fails to positively set forth a flexible cannula or any cannula.

Applicants respectfully submit that the amendments made herein render this rejection moot and that the claims comply with 35 U.S.C. §112, second paragraph.

#### 4. 35 U.S.C. §102 Rejections

Claims 1-4, 12-16, 19 and 25-33 have been rejected under 35 U.S.C. §102(e) as being anticipated by Le et al (US Pat# 6,355,027).

While Applicants fully disagree with these rejections, Applicants respectfully submit that these rejections are overcome in view of the amendments set forth herein.

#### 5. 35 U.S.C. §103 Rejections

Claims 5-7 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Le in view of Weiss (US Pat# 6,042,734).

While Applicants fully disagree with these rejections, Applicants respectfully submit that these rejections are overcome in view of the amendments set forth herein.

### **CONCLUSION**

Reconsideration and allowance of claims 1-19, 21-35 and 39-57 is respectfully requested in view of the foregoing discussion. This case is believed to be in condition for immediate allowance. Applicants respectfully requests early consideration and allowance of the subject application.

Applicants believe that no extension of time is required since this response is being filed before the expiration of the specified time period. Applicants, however, conditionally petition for an extension of time to provide for the possibility that such a

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petition has been inadvertently overlooked and is required. As provided below charge Deposit Account No. **04-1105** for any required fee.

Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned attorney would appreciate the opportunity to do so.

Respectfully submitted,



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**VERSION WITH MARKINS TO SHOW CHANGES MADE IN SPECIFICATION**

Please note that additions to the specification are shown underlined and deletions are shown in brackets.

At page 14, lines 1-10:

In another embodiment shown in Fig. 3, a metal portion 28 is mounted on the cannula 2 by, for example, epoxying the metal portion 28 to the cannula 2. The metal portion 28 could then be grasped by forceps or by an electromagnet 30 during manipulation and insertion of the cannula 2 within the retinal vein.

In another embodiment shown in Fig. 4, a wire [30] 32 is mounted on the cannula 2. During manipulation and insertion of the cannula 2 within the retinal vein, the wire 30 may be grasped by forceps or similar grasping means.

At page 15, lines 1-7:

infusion fluid passes from the syringe, through the larger cannula 14, through the smaller cannula 2 and into the occluded retinal vessel. As such, the larger cannula 14 forms a fluid-tight seal about cannula 2 to prevent leakage of infusion fluid between the larger cannula 14 and cannula 2. In a preferred embodiment, the larger cannula 14 [12] has an outer diameter that ranges from about 400  $\mu\text{m}$  to about 800  $\mu\text{m}$ , and, more preferably, about 556  $\mu\text{m}$ .

**VERSION WITH MARKINS TO SHOW CHANGES MADE IN CLAIMS**

Please note that additions to the claims are shown underlined and deletions are shown in brackets.

1. A microcatheter system for infusion of a solution into a retinal vein, wherein the microcatheter system remains within the retinal vein during the infusion without an external holding device for at least a period of time required for a bolus injection, wherein the microcatheter system comprises a modified microcannula system in which a flexible cannula and a second cannula are mounted, and wherein the microcannula system further includes an inner plug mounted on the modified microcannula system.

2. A microcatheter system comprising:

a flexible cannula for insertion into a retinal vein lumen, whereby a solution is infused into the retinal vein lumen through the flexible cannula and the flexible cannula remains within the retinal vein lumen during the infusion without an external holding for at least a period of time required for a bolus injection; and

a second cannula, wherein the microcatheter system comprises a modified microcannula system in which a flexible cannula and a second cannula are mounted, and wherein the microcannula system further includes an inner plug mounted on the modified microcannula system.

3. A microcatheter system comprising:

a flexible cannula for insertion into a retinal vein lumen, whereby a solution is infused into the retinal vein lumen through the flexible cannula and the flexible cannula remains within the retinal vein lumen during the infusion without an external holding device;

and

a second cannula, wherein the microcatheter system comprises a modified microcannula system in which a flexible cannula and a second cannula are mounted, and wherein the microcannula system further includes an inner plug mounted on the modified microcannula system.

21. The microcatheter system of any one of claims 1 through 3 [20], wherein the inner plug is fabricated of silicone.

22. The microcatheter system of any one of claims 1 through 3 [20], wherein the inner plug has an aperture through which the second cannula and flexible cannula are inserted.

23. The microcatheter system of any one of claims 1 through 3 [20], wherein the inner plug forms a fluid-tight seal about the second cannula.

39. A method for manual retinal vein catheterization comprising [using the microcatheter system of any one of claims 1 through 3 by] inserting [the] a microcatheter system [or cannula] within a retinal vein [in an eye] and infusing solution into the retinal vein, whereby the microcatheter system [or cannula] remains within the retinal vein without an external holding device.